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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,328

04/13/2004

Mark A. Roehrig

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3M INNOVATIVE PROPERTIES COMPANY  
PO BOX 33427  
ST. PAUL, MN 55133-3427

EXAMINER

MAEWALL, SNIGDHA

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

12/20/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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LegalDocketing@mmm.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/823,328	ROEHRIG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Snigdha Maewall	1612	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 June 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 10, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 10 and 13-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### Summary

1. Receipt of Applicants arguments, amended claims and **RCE** filed on 06/22/10 is acknowledged.

Claim 1 has been amended. Claims 5-9 and 15-20 remain withdrawn. Claims 2- 4, 11-12 have been cancelled.

Claims **1, 10 and 13-14** are under prosecution.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 10 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pilgaard et al. (US PG pub. 20050019383) in view of Shaw et al. (USP 6231939) and further in view of CZEREMUSZKIN et al. (WO 03/016589 A1, herein onwards '589).

Pilgaard et al. teaches patches for dermal and transdermal drug delivery (abstract). The reference teaches barrier layer separating the active ingredient from the

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adhesive. The barrier layer may be in the form of a polymer or a metal layer impermeable to the active ingredient and to the adhesive layer (see page 1, paragraph [0004]). The article has adhesive layer which adheres to skin, which has a first component constituting a continuous layer and at least a second component which is located in indentations in the adhesive surface of the first component and the second component is separated by barrier layer (see paragraph [0016], page 1). The second component may act as reservoir. (See paragraph [0022]). The barrier layer may be arranged in a pattern over the dressing in order to distribute the active ingredient in a desired way (see paragraph [0048] on page 3). The barrier layer comprises a metal foil which could be aluminum or a laminate of one or more layers or plurality of barrier layers (see paragraphs [0025, 0026, 0028 and 0048] on pages 2 and 3. The article comprises a backing layer which may be polyurethane film or foam or combination of film layers (see paragraph [0051]), (instant specification exemplifies polyurethane as one of the components constituting the backing layer, see page 8 second paragraph). (Reads on backing film substrate), (thus the backing film will be translucent since the prior art and the instant disclosure both disclose backing film material to be polyurethane). The flange which is a continuation of barrier layer is taught to be of an average thickness of less than about 0.045 mm (see page 1, paragraph [0016]). Therefore, regarding the claimed size of the barrier layer, it is the position of the examiner that optimization of such parameter would have been within the purview of a skilled artisan absent evidence of any unexpected results associated with the claimed thickness.

Although the reference discloses the barrier layer as constituting metal foil, it does not specifically disclose barrier layers with aluminum oxide or other metal oxides as claimed in instant claim 1.

Shaw et al. disclose deposition of barrier films for inhibiting penetration by oxygen or other gases employing a cross-linked acrylate layer and a layer of oxygen barrier material see column, 1 line 14-17. The reference further teaches that a transparent barrier film may be formed on a polyethylene, polypropylene, polyester or nylon substrate, or other thermoplastic substrate. First, a layer of acrylate monomer is deposited on the substrate and cross linked. The acrylate layer is then coated with an oxygen barrier layer of silicon oxide and aluminum oxide, both of which have good resistance to oxygen permeability. The high temperature resistance of the cross linked acrylate layer permits the notably higher temperature deposition of silicon oxide or aluminum oxide on the thermoplastic substrate see column, 3 lines 14-22.

It would have been obvious to one of ordinary skill to have incorporated a barrier layer comprising aluminum oxide or silicon oxide in the teachings of primary reference in order to have good resistance to oxygen permeability motivated by the teachings of secondary reference.

Furthermore, it would have been obvious to one of ordinary skilled in the art to modify the application of barrier layer and make it substantially continuous since the prior art by Pilgaard teaches that the barrier layer may be arranged in a pattern over the dressing in order to distribute the active ingredient in a desired way and Shaw teaches barrier films comprising aluminium oxide which provides resistance to oxygen

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permeability. Substitution of one known film with another to provide predictable results would have been obvious to one of ordinary skill in the art to obtain predictable results. Since the material used in barrier layer of Shaw is same as the claimed barrier layer, the property of the layer being translucent would not be excluded because property of a compound cannot be separated from the chemistry of the compound.

The references in combination do not explicitly teach the thickness of inorganic barrier layer to be greater than 10 nm and less than 100 nm.

CZEREMUSZKIN et al. teach coatings with low permeation of gases and vapors, title. The multilayer structure has barrier properties for gas and vapors for instant oxygen and water vapor, the barrier layer comprises inorganic coating, abstract. Such coatings replace glass in food and pharmaceutical packaging and in electronics applications, see page 1, lines 10-13. The coating material is indium-tin oxide which is transparent material, see page 1, lines 18-20. The coating act as protective coatings against attack by liquids, gases and vapors, see page 1, lines 12-13. The coating has transparent properties, page 2; lines 19-20. The coatings are impermeable to gases when formed as a continuous coatings, see page 7, and lines 16-18. The thickness of inorganic coating have thickness of 1nm to 1 micron, preferably from 10nm to 350 nm and can from 40nm t to 350nm, see page 7, lines 11-16. Silicon dioxide is also used as inorganic coating material on page 27 example 1.

It would have been obvious to one of ordinary skill to have incorporated an inorganic barrier layer comprising indium tin oxide or silicon oxide in the teachings of the references discussed above because CZEREMUSZKIN et al. teach that inorganic

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coatings comprising silicon dioxide or indium tin oxide provide protection against gases and vapors and may provide applications in food and pharmaceutical packaging and also describe the inorganic layer to be transparent. Since the thickness of the inorganic coating is described to be from 1 nm to 350 nm, one of ordinary would work with the thickness in order to achieve optimum thickness for better protection against oxygen, gases and vapors. Regarding the device being translucent, since the components of the transdermal device of the prior art, the inorganic barrier layer and backing layer and the thickness of the layer is substantially similar to the claimed layers, one of ordinary would expect the property of the layers being translucent. Patent office is not equipped with laboratory the conduct experiments, burden is on applicant to prove otherwise. Absent evidence of unexpected results and based on the teachings of the prior art , it would have been obvious to one of ordinary skilled in the art at the time of the instant invention to prepare a transdermal drug delivery device comprising reservoir, a barrier layer and backing layer with a reasonable expectation of success.

### ***Response to Arguments***

4. Applicant's arguments with respect to claims 1, 10 and 13-14 have been considered but are moot in view of the new ground(s) of rejection.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-

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272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612